of the Federal Food, Drug, and Cosmetic Act on the date that is the later of—

(i) the date that is 1 year after the date of enactment of this Act; or

(ii) such date as the Secretary may specify under subsection (a)(3) of that section;

unless the Secretary grants a waiver under subsection (a)(4) of that section.

On page 19, line 7, strike ''(b)'' and insert ''(c)''.

SA 1361. Mrs. HUTCHISON (for herself, Mr. VOINOVICH, Mr. DEWINE, Mr. SPECTER, Mr. SANTORUM, and Mr. WARNER) submitted an amendment intended to be proposed by her to the bill H.R. 2555, making appropriations for the Department of Homeland Security for the fiscal year ending September 30, 2004, and for other purposes; which was ordered to lie on the table; as follows:

On page 75, between lines 5 and 6, insert the following:

SEC. 6___. PAYMENTS BASED ON POPULATION.

(a) DEFINITIONS.—In this section:

(1) RELATIVE STATE POPULATION PROPORTION.—The term ''relative State population proportion'' means, with respect to a State, the amount that is equal to the quotient obtained by dividing—

(A) the population of the State (as reported in the most recent decennial census); by

(B) the total population of all States (as reported in the most recent decennial census).

(2) RELATIVE POPULATION PROPORTION AMOUNT.—The term ''relative population proportion amount'' means the product of—

(A) the appropriated amount described in subsection (b); and

(B) the relative State population proportion for the State.

(3) STATE.—The term ''State'' means each of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, the Commonwealth of the Northern Mariana Islands, and American Samoa.

(b) PAYMENTS.—Subject to subsection (c), the amount appropriated under paragraph (1) under the heading ''STATE AND LOCAL PROGRAMS'' under the heading ''OFFICE FOR DOMESTIC PREPAREDNESS'' in title IV shall be used to pay each State an amount equal to the relative population proportion amount.

(c) MINIMUM PAYMENT.—

(1) IN GENERAL.—No State shall receive a payment under this section for a fiscal year that is less than—

(A) in the case of 1 of the 50 States or the District of Columbia, ½ of 1 percent of the appropriated amount described in subsection (b); and

(B) in the case of the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, the Commonwealth of the Northern Mariana Islands, or American Samoa, ⅒ of 1 percent of the appropriated amount described in subsection (b).

(2) PRO RATA ADJUSTMENTS.—The Secretary of the Treasury shall adjust, on a pro rata basis, the amount of the payments to States determined under this section without regard to this paragraph to the extent necessary to comply with the requirements of paragraph (1).

AUTHORITY FOR COMMITTEES TO MEET

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

Mr. COCHRAN. Mr. President, I ask unanimous consent that the Committee on Commerce, Science, and Transportation be authorized to meet on Wednesday, July 23, 2003, at 9:30 a.m. on Public Interest and Localism in SR–253.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON ENERGY AND NATURAL RESOURCES

Mr. COCHRAN. Mr. President, I ask unanimous consent that the Committee on Energy and Natural Resources be authorized to meet during the session of the Senate, on Wednesday, July 23 at 10 a.m. to consider pending calendar business.

Agenda

Agenda Item 2: S. 391—A bill to enhance ecosystem protection and the range of outdoor opportunities protected by statute in the Skykomish River valley of the State of Washington by designating certain lower-elevation Federal lands as wilderness, and for other purposes.

Agenda Item 3: S. 434—A bill to authorize the Secretary of Agriculture to sell or exchange all or part of certain parcels of National Forest System land in the State of Idaho and use the proceeds derived from the sale or exchange for National Forest System purposes.

Agenda Item 4: S. 435—A bill to provide for the conveyance by the Secretary of Agriculture of the Sandpoint Federal Building and adjacent land in Sandpoint, Idaho, and for other purposes.

Agenda Item 5: S. 452—A bill to require that the Secretary of the Interior conduct a study to identify sites and resources, to recommend alternatives for commemorating and interpreting the Cold War, and for other purposes.

Agenda Item 6: S. 714—A bill to provide for the conveyance of a small parcel of Bureau of Land Management land in Douglas County, Oregon, to the county to improve management of and recreational access to the Oregon Dunes National Recreation Area, and for other purposes.

Agenda Item 9: S. 1003—A bill to clarify the intent of Congress with respect to the continued use of established commercial outfitter hunting camps on the Salmon River.

Agenda Item 10: H.R. 417—To revoke a Public Land Order with respect to certain lands erroneously included in the Cibola National Wildlife Refuge, California.

Agenda Item 11: H.R. 622—To provide for the exchange of certain lands in the Coconino and Tonto National Forests in Arizona, and for other purposes.

Agenda Item 12: H.R. 762—To amend the Federal Land Policy and Management Act of 1976 and the Mineral Leasing Act to clarify the method by which the Secretary of the Interior and the Secretary of Agriculture determine the fair market value of certain rights-of-way granted, issued, or renewed under these Acts.

Agenda Item 13: H.R. 1012—To establish the Carter G. Woodson Home National Historic Site in the District of Columbia, and for other purposes.

In addition, the Committee may turn to any other measures that are ready for consideration.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON FOREIGN RELATIONS

Mr. COCHRAN. Mr. President, I ask unanimous consent that the Committee on Foreign Relations be authorized to meet during the session of the Senate on Wednesday, July 23, 2003 at 9:30 a.m. to hold a Business Meeting.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON FOREIGN RELATIONS

Mr. COCHRAN. Mr. President, I ask unanimous consent that the Committee on Foreign Relations be authorized to meet during the session of the Senate on Wednesday, July 23, 2003 at 2:45 p.m. to hold a hearing on Iraq: Status and Prospects for Reconstruction—Next Steps.

The PRESIDING OFFICER. Without objection, it so ordered.

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

Mr. COCHRAN. Mr. President, I ask unanimous consent that the Committee on Health, Education, Labor, and Pensions be authorized to meet in Executive Session during the session of the Senate on Wednesday, July 23, 2003.

Agenda

S.__, Patient Safety and Quality Improvement Act of 2003

Presidential Nominations: Daniel Pipes, of Pennsylvania, to be a Member of the Board of Directors of the United States Institute of Peace; Charles Edward Horner, of the District of Columbia, to be a Member of the Board of Directors of the United States Institute of Peace; Stephen David Krasner, of California, to be a Member of the Board of Directors of the United States Institute of Peace; Eric Dreiband, of Virginia, to be General Counsel of the Equal Employment Opportunity Commission.

Any additional nominees cleared for action.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON INDIAN AFFAIRS

Mr. COCHRAN. Mr. President, I ask unanimous consent that the Committee on Indian Affairs be authorized to meet on Wednesday, July 23, 2003, at 10:00 a.m. in Room 485 of the Russell Senate Office Building to conduct a hearing on S. 556, a Bill to Reauthorize the Indian Health Care Improvement Act.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON THE JUDICIARY

Mr. COCHRAN. Mr. President, I ask unanimous consent that the Committee on the Judiciary be authorized to meet to conduct a markup on Wednesday, July 23, 2003, at 9:00 a.m. in Hart Room 216.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON THE JUDICIARY

Mr. COCHRAN. Mr. President, I ask unanimous consent that the Committee on the Judiciary be authorized to meet to conduct a hearing on ''Oversight Hearing: Law Enforcement and Terrorism'' on Wednesday, July 23, 2003, at 10:00 a.m. in the Hart Senate Office Building Room 216.

Agenda

The Honorable Robert S. Mueller, Director, Federal Bureau of Investigation, Department of Justice, Washington, DC; The Honorable Asa Hutchinson, Under Secretary for Border & Transportation Security, Department of Homeland Security, Washington, DC.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON THE JUDICIARY

Mr. COCHRAN. Mr. President, I ask unanimous consent that the Committee on the Judiciary be authorized to meet to conduct an Executive Nominations hearing on Wednesday, July 23, 2003, at 2:00 p.m. in the Dirksen Senate Office Building Room 226.

Agenda

Panel I: Senators.

Panel II: Rene Alexander Acosta to be Assistant Attorney General, Civil Rights Division, United States Department of Justice and Daniel J. Bryant to be Assistant Attorney General, Office of Legal Policy, United States Department of Justice.

The PRESIDING OFFICER. Without objection, it is so ordered.

SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY, AND CONSUMER RIGHTS

Mr. COCHRAN. Mr. President, I ask unanimous consent that the Senate Committee on the Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights be authorized to meet to conduct a hearing on ''Agriculture, Consolidation and the Smithfield/Farmland Deal'' on Wednesday, July 23, 2003, at 4:00 p.m. in Room 138 of the Dirksen Senate Office Building.

Agenda

Panel I: Senator Tim Johnson.

Panel II: Mr. Joseph Sebring, CEO, John Morrell, Inc., Cincinnati, OH; Mr. William Hughes, Administrator, Division of Agricultural Development, Wisconsin Department of Agriculture, Trade and Consumer Protection, Madison, WI; Dr. Luther Tweeten, Agriculture Consultant, Columbus, OH; Mr. Russ Kremer, President, Missouri Farmers' Union, Jefferson City, MO; Mr. Patrick Bell, Farmer, Kenansville, NC; and Mr. Michael Stumo, General Counsel, Organization for Competitive Markets, Winstead, CT.

The PRESIDING OFFICER. Without objection, it is so ordered.

SUBCOMMITTEE ON HOUSING AND TRANSPORTATION

Mr. COCHRAN. Mr. President, I ask unanimous consent that the Subcommittee on Housing and Transportation of the Committee on Banking, Housing, and Urban Affairs be authorized to meet during the session of the Senate on July 23, 2003, at 2:30 p.m. to conduct a hearing on ''Enhancing the Role of the Private Sector in Public Transportation.''

The PRESIDING OFFICER. Without objection, it is so ordered.

PRIVILEGE OF THE FLOOR

Mr. BAUCUS. Mr. President, I ask unanimous consent that Jeff Klein and Matt Linstroth of my staff be granted the privilege of the floor for the day.

The PRESIDING OFFICER. Without objection, it is so ordered.

PEDIATRIC RESEARCH EQUITY ACT OF 2003

Mr. DEWINE. Mr. President, I ask unanimous consent the Senate proceed to the immediate consideration of calendar 183, S. 650.

The PRESIDING OFFICER. The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (S. 650) to amend the Federal Food, Drug, and Cosmetic Act to authorize the Food and Drug Administration to require certain research into drugs used in pediatric patients.

There being no objection, the Senate proceeded to consider the bill which had been reported from the Committee on Health, Education, Labor, and Pensions, with amendments, as follows:

[Strike the part shown in black brackets and insert the part shown in italic.]

S. 650

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Pediatric Research Equity Act of 2003''.

SEC. 2. RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PRODUCTS.

(a) IN GENERAL.—Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505A the following:

''SEC. 505B. RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PRODUCTS.

''(a) NEW DRUGS AND BIOLOGICAL PRODUCTS.—

''(1) IN GENERAL.—A person that submits an application (or supplement to an application)—

''(A) under section 505 for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration; or

''(B) under section 351 of the Public Health Service Act (42 U.S.C. 262) for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration;

shall submit with the application the assessments described in paragraph (2).

''(2) ASSESSMENTS.—

''(A) IN GENERAL.—The assessments referred to in paragraph (1) shall contain data, gathered using appropriate formulations for each age group for which the assessment is required, that are adequate—

''(i) to assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations; and

''(ii) to support dosing and administration for each pediatric subpopulation for which the drug or the biological product is safe and effective.

''(B) SIMILAR COURSE OF DISEASE OR SIMILAR EFFECT OF DRUG OR BIOLOGICAL PRODUCT.—

''(i) IN GENERAL.—If the course of the disease and the effects of the drug are sufficiently similar in adults and pediatric patients, the Secretary may conclude that pediatric effectiveness can be extrapolated from adequate and well-controlled studies in adults, usually supplemented with other information obtained in pediatric patients, such as pharmacokinetic studies.

''(ii) EXTRAPOLATION BETWEEN AGE GROUPS.—A study may not be needed in each pediatric age group if data from 1 age group can be extrapolated to another age group.

''(3) DEFERRAL.—On the initiative of the Secretary or at the request of the applicant, the Secretary may defer submission of some or all assessments required under paragraph (1) until a specified date after approval of the drug or issuance of the license for a biological product if—

''(A) the Secretary finds that—

''(i) the drug or biological product is ready for approval for use in adults before pediatric studies are complete;

''(ii) pediatric studies should be delayed until additional safety or effectiveness data have been collected; or

''(iii) there is another appropriate reason for deferral; and

''(B) the applicant submits to the Secretary—

''(i) certification of the grounds for deferring the assessments;

''(ii) a description of the planned or ongoing studies; and

''(iii) evidence that the studies are being conducted or will be conducted with due diligence and at the earliest possible time.

''(4) WAIVERS.—

''(A) FULL WAIVER.—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments for a drug or biological product under this subsection if the applicant certifies and the Secretary finds that—

''(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients is so small or the patients are geographically dispersed);

''(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups; or

''(iii) the drug or biological product—

''(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and

''(II) is not likely to be used in a substantial number of pediatric patients.

''(B) PARTIAL WAIVER.—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments for a drug or biological product under this subsection with respect to a specific pediatric age group if the applicant certifies and the Secretary finds that—

''(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed);

''(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;

''(iii) the drug or biological product—

''(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and

''(II) is not likely to be used by a substantial number of pediatric patients in that age group; or

''(iv) the applicant can demonstrate that reasonable attempts to produce a pediatric